

WHAT IS CLAIMED IS:

1. A method for enhancing dispersion of drug-containing particles in an aqueous medium, the method comprising providing a solid dosage form of the drug having incorporated therein a dispersion-enhancing amount of an effervescent agent, wherein (a) the dosage form is adapted for swallowing without prior disintegration in water or in the mouth, and (b) the amount of the effervescent agent is not sufficient to substantially enhance disintegration of the dosage form in the aqueous medium.

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2. The method of Claim 1 wherein the drug is of low water solubility.

10 3. The method of Claim 1 wherein the rate of dissolution of the drug in the aqueous medium is enhanced.

4. The method of Claim 1 wherein the effervescent agent generates oxygen or carbon dioxide gas upon contact with water.

5. The method of Claim 1 wherein the dosage form is selected from the group consisting of a tablet, caplet, capsule, drug powder or powder blend.

15 6. The method of Claim 1 wherein the effervescent agent comprises an acid component and a base component.

7. The method of Claim 6 wherein the acid component comprises at least one acid selected from the group consisting of citric acid, tartaric acid, malic acid, fumaric acid, adipic acid, succinic acid, acid anhydrides and acid salts thereof, and mixtures thereof.

20 8. The method of Claim 7 wherein the at least one acid is citric acid.

9. The method of Claim 6 wherein the base component comprises at least one base selected from the group consisting of carbonate salts, bicarbonate salts, sesquicarbonate salts, and mixtures thereof.

25 10. The method of Claim 9 wherein the at least one base is calcium carbonate.

11. The method of Claim 6 wherein the weight ratio of the acid component to the base component in the effervescent agent is about 1:100 to about 100:1.

12. The method of Claim 6 wherein the weight ratio of the acid component to the

base component in the effervescent agent is about 1:50 to about 50:1.

13. The method of Claim 6 wherein the weight ratio of the acid component to the base component in the effervescent agent is about 1:10 to about 10:1.
14. The method of Claim 6 wherein the ratio of the acid component to the base component in the effervescent agent is approximately stoichiometric.
- 5 15. The method of Claim 1 wherein the effervescent agent is present in the dosage form in an amount of about 1% to about 20% by weight.
16. The method of Claim 1 wherein the effervescent agent is present in the dosage form in an amount of about 2% to about 15% by weight.
- 10 17. The method of Claim 1 wherein the effervescent agent is present in the dosage form in an amount of about 3% to about 10% by weight.
18. A solid pharmaceutical composition comprising a therapeutically and/or prophylactically effective amount of a drug and a dispersion-enhancing amount of an effervescent agent, wherein (a) the dosage form is adapted for swallowing without prior disintegration in water or in the mouth, and (b) the amount of the effervescent agent is not sufficient to substantially enhance disintegration of the dosage form in an aqueous medium.
- 15 19. The composition of Claim 18 wherein the drug is of low water solubility.
20. The composition of Claim 18 wherein the rate of dissolution of the drug in an aqueous medium is enhanced.
- 20 21. The composition of Claim 18 wherein the effervescent agent generates oxygen or carbon dioxide gas upon contact with water.
22. The composition of Claim 18 that is a dosage form selected from the group consisting of a tablet, a caplet, a capsule, a drug powder and a powder blend.
- 25 23. The composition of Claim 18 wherein the effervescent agent comprises an acid component and a base component.
24. The composition of Claim 23 wherein the acid component comprises at least one acid selected from the group consisting of citric acid, tartaric acid, malic acid, fumaric acid, adipic acid, succinic acid, acid anhydrides and acid salts thereof,

and mixtures thereof.

25. The composition of Claim 24 wherein the at least one acid is citric acid.

26. The composition of Claim 23 wherein the base component comprises at least one base selected from the group consisting of carbonate salts, bicarbonate salts, sesquicarbonate salts, and mixtures thereof.

27. The composition of Claim 26 wherein the at least one base is calcium carbonate.

28. The composition of Claim 23 wherein the weight ratio of the acid component to the base component in the effervescent agent is about 1:100 to about 100:1.

29. The composition of Claim 23 wherein the weight ratio of the acid component to the base component in the effervescent agent is about 1:50 to about 50:1.

30. The composition of Claim 23 wherein the weight ratio of the acid component to the base component in the effervescent agent is about 1:10 to about 10:1.

31. The composition of Claim 23 wherein the ratio of the acid component to the base component in the effervescent agent is approximately stoichiometric.

15 32. The composition of Claim 18 wherein the effervescent agent is present in the composition in an amount of about 1% to about 20% by weight.

33. The composition of Claim 18 wherein the effervescent agent is present in the composition in an amount of about 2% to about 15% by weight.

34. The composition of Claim 18 wherein the effervescent agent is present in the composition in an amount of about 3% to about 10% by weight.

20 35. A solid pharmaceutical dosage form comprising a therapeutically and/or prophylactically effective amount of a drug and a dispersion-enhancing amount of an effervescent agent, wherein the dosage form does not exceed about 800 mg in total weight.

25 36. The dosage form of Claim 35 wherein said dosage form has a total weight of about 100 to about 750 mg.

37. The dosage form of Claim 35 wherein said dosage form has a total weight of about 200 to about 700 mg.

38. The composition of Claim 35 wherein the drug is of low water solubility.

39. The composition of Claim 35 wherein the rate of dissolution of the drug in an aqueous medium is enhanced.

40. The composition of Claim 35 wherein the effervescent agent generates oxygen or carbon dioxide gas upon contact with water.

5 41. The composition of Claim 35 that is a dosage form selected from the group consisting of a tablet, a caplet, a capsule, a drug powder and a powder blend.

42. The composition of Claim 35 wherein the effervescent agent comprises an acid component and a base component.

43. The composition of Claim 42 wherein the acid component comprises at least one acid selected from the group consisting of citric acid, tartaric acid, malic acid, fumaric acid, adipic acid, succinic acid, acid anhydrides and acid salts thereof, and mixtures thereof.

10 44. The composition of Claim 43 wherein the at least one acid is citric acid.

45. The composition of Claim 42 wherein the base component comprises at least one base selected from the group consisting of carbonate salts, bicarbonate salts, sesquicarbonate salts, and mixtures thereof.

15 46. The composition of Claim 45 wherein the at least one base is calcium carbonate.

47. The composition of Claim 42 wherein the weight ratio of the acid component to the base component in the effervescent agent is about 1:100 to about 100:1.

20 48. The composition of Claim 42 wherein the weight ratio of the acid component to the base component in the effervescent agent is about 1:50 to about 50:1.

49. The composition of Claim 42 wherein the weight ratio of the acid component to the base component in the effervescent agent is about 1:10 to about 10:1.

50. The composition of Claim 42 wherein the ratio of the acid component to the base component in the effervescent agent is approximately stoichiometric.

25 51. The composition of Claim 35 wherein the effervescent agent is present in the composition in an amount of about 1% to about 20% by weight.

52. The composition of Claim 35 wherein the effervescent agent is present in the composition in an amount of about 2% to about 15% by weight.

53. The composition of Claim 35 wherein the effervescent agent is present in the composition in an amount of about 3% to about 10% by weight.

54. A process for preparing a composition of Claim 18, the process comprising

- (a) providing the drug in finely divided form;
- 5 (b) admixing the finely divided drug with an effervescent agent and optionally with one or more pharmaceutically acceptable excipients to form a mixture; and
- (c) applying mechanical means to the mixture to form a drug powder wherein the drug and the effervescent agent are in intimate association.

10 55. The process of Claim 54 further comprising

- (d) blending the drug powder with one or more excipients to form a blend; and
- (e) compressing the blend to form tablets.

15 56. The process of Claim 54 further comprising

- (d) blending the drug powder with one or more excipients to form a blend; and
- (e) encapsulating the blend to form capsules.

57. The process of Claim 54 wherein the mechanical means is selected from the group consisting of milling, grinding, blending, spray drying and granulating.

58. A process for preparing a composition of Claim 35, the process comprising

- (a) providing the drug in finely divided form;
- 20 (b) admixing the finely divided drug with an effervescent agent and optionally with one or more pharmaceutically acceptable excipients to form a mixture; and
- (c) applying mechanical means to the mixture to form a drug powder wherein the drug and the effervescent agent are in intimate association.

25 59. The process of Claim 58 further comprising

- (d) blending the drug powder with one or more excipients to form a blend; and
- (e) compressing the blend to form tablets.

60. The process of Claim 58 further comprising

- (d) blending the drug powder with one or more excipients to form a blend; and
- 30 (e) encapsulating the blend to form capsules.

61. The process of Claim 58 wherein the mechanical means is selected from the group consisting of milling, grinding, blending, spray drying and granulating.

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